IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC., Defendants.	)	Civil Action No. 03-027-SLR
BOSTON SCIENTIFIC SCIMED, INC. and BOSTON SCIENTIFIC CORPORATION, Plaintiffs, v. CORDIS CORPORATION and JOHNSON & JOHNSON, INC., Defendants.	)	Civil Action No. 03-283-SLR

MEMORANDUM ORDER

At Wilmington this 21st day of November, 2003, having reviewed the papers submitted in connection with the parties' cross motions for the preliminary imposition of injunctive relief, and having conducted an evidentiary hearing in connection with said motions;

IT IS ORDERED that both said motions are denied, for the reasons that follow.

1. **Standard of Review.** As the Federal Circuit has recognized, a preliminary injunction is "a drastic and extraordinary remedy that is not to be routinely granted." Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993). To obtain such extraordinary relief, the movant must prove that: 1) it has a reasonable likelihood of success on the merits; 2) it would suffer irreparable harm if the injunction were not granted; 3) the balance of relative hardships weighs in its favor; and 4) an injunction would not have a negative impact on the public interest. See New England Braiding Co., Inc. v. A.W. Chesterton Co., 970 F.2d 878, 882 (Fed. Cir. 1992).

2. **Background.** The parties in this related litigation, competitors in the extremely lucrative field of coronary stents, are well known to the court and to each other. The litigation now pending before the court represents the next chapter in the evolution of the stent market, i.e., drug-eluting stents. The question before the court is whether the patent rights asserted by either party outweigh the other interests which must be evaluated by the court, including the public's interest in having the best technology available to it through a competitive market.

3. **Cordis Corporation's motion for a preliminary injunction.** Cordis Corporation ("Cordis") urges the court to impose an injunction against Boston Scientific Corporation and

Scimed Life Systems, Inc. (collectively "BSC"), alleging that BSC's drug-eluting stent, TAXUS, literally infringes claim 23 of U.S. Patent No. 4,739,762 (the "'762 patent").

a. **Likelihood of success on the merits.** Claim 23 of the '762 patent is an apparatus claim which depends from claim 13. The claims read:

> 13. An expandable intraluminal vascular graft, comprising:
> a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;
> the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and
> the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.
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> 23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

('762 patent, col. 11, ll. 63 - col. 12, ll. 14; col. 12, ll. 56-59)

Having the benefit of the Federal Circuit's claim construction[1] and the presentation of expert testimony consistent therewith,[2] the court concludes that Cordis has carried its burden of proving that it would likely succeed in proving that BSC's TAXUS stent infringes claim 23 of the '762 patent.

b. **Irreparable harm to Cordis.** Despite the presumption of irreparable harm that arises from a showing of likely success on the merits, the court finds that the presumption has been rebutted by the following record. First, the court notes that BSC's TAXUS drug-eluting stent incorporates BSC's bare metal EXPRESS stent.[3] Despite the fact that Cordis knew by September 2001 that the EXPRESS stent would serve as the platform for TAXUS, Cordis did not file suit seeking injunctive relief until January 2003. Second, Cordis is willing to seek money damages after trial on the merits for infringement by the EXPRESS stent. Third, Cordis has licensed major competitors under the asserted '762 patent and has admitted that several of these competitors could make a drug-eluting stent without infringing the '762 patent. Finally, the evidence shows that the

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[1]See Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352 (Fed. Cir. 2003).

[2]See the July 21, 2003 hearing transcript at 104-120.

[3]The only other components of TAXUS are the paclitaxel drug and a polymer system. Cordis has not asserted a patent covering either of these components.

entire drug-eluting stent market in the United States would comprise only about five percent of Johnson & Johnson's total sales. For all of these reasons, the court concludes that the presumption of irreparable harm has been rebutted.

c. **Irreparable harm to BSC.** Cordis has failed to prove that BSC will not suffer irreparable harm if it were enjoined from marketing its TAXUS drug-eluting stent. The record demonstrates that an injunction would likely cut BSC's workforce, threaten its most important business, and disrupt BSC's ability to develop new therapeutic devices. In addition, because TAXUS is manufactured in the United States but is being used outside the United States, an injunction would put at risk the ability of patients worldwide to use TAXUS.

d. **Harm to the public.** Aside from the obvious concern of depriving the public of the best and safest medical devices by limiting competition, it is apparent from the evidence that Cordis cannot ensure an adequate supply of drug-eluting stents to meet current market demand.

e. **Conclusion.** For the reasons stated above, the court concludes that Cordis has failed to carry its burden of proof on three of the four prongs of the analysis. The '762 patent, ground-breaking as it was decades ago, contributes nothing to the inventive aspects of drug-eluting stents. Keeping in mind that the entry of injunctive relief is an equitable

remedy, the court finds it would be inequitable to grant such drastic relief based on patented old technology when it is new unpatented technology driving the business decision to file suit. Therefore, Cordis' motion for entry of a preliminary injunction is denied.

4. **BSC's motion for a preliminary injunction.** In its motion for injunctive relief, BSC contends that Cordis' CYPHER stent literally infringes claim 8 of U.S. Patent No. 6,120,536 (the "536 patent").

a. **Likelihood of success on the merits.** Claim 8 depends from claim 6 which, in turn, depends from claim 1. These claims read:

> 1. A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material, wherein said coating comprises an undercoat comprising a hydrophobic elastomeric material incorporating an amount of biologically active material therein for timed release therefrom, and wherein said coating further comprises a topcoat which at least partially covers the undercoat, said topcoat comprising a biostable, non-thrombogenic material which provides long term non-thrombogenicity to the device portion during and after release of the biologically active material, and wherein said topcoat is substantially free of an elutable material.
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> 6. The device of claim 1 wherein the medical device is an expandable stent.
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> 8. The device of claim 6 wherein the stent comprises a tubular body having open ends and

> an open lattice sidewall structure and wherein the coating conforms to said sidewall structure in a manner that preserves said open lattice.

('536 patent, col. 13, ll. 13-26, ll. 37-38, col. 14., ll. 1-4)

At the evidentiary hearing, the parties focused on two limitations.

(1) The first limitation is "non-thrombogenic." BSC argues that non-thrombogenic describes a material that does not promote thrombus formation. Consistent with this claim interpretation, BSC contends that Cordis' CYPHER stent meets this limitation based on representations made to the FDA by Cordis that CYPHER's polymer coating is a non-thrombogenic polymer. Cordis denies infringement, arguing that the '536 patent claims not only a coating that is non-thrombogenic, but that such coating must render the stent non-thrombogenic over the long term. Cordis asserts that its CYPHER stent is as thrombogenic as bare metal stents and, therefore, cannot literally meet this limitation.

(2) The second limitation in dispute is that the topcoat of the device be "substantially free of an elutable material." BSC contends that this limitation should be construed to mean "largely free, but not necessarily completely free of elutable material." Cordis offers no construction, but argues that, "whatever the claim term means, BSC (as the party seeking an injunction) has the burden of presenting the fact-finder with

evidence about the amount of elutable material in the top coat so that the Court can determine whether the claim term is, or is not, met. BSC acknowledges that sirolimus[4] is present in the top layer, but it offered no proof whatsoever about how much." (C.A. No. 03-027-SLR, D.I. 88 at 24) BSC counters with representations made by Cordis to the medical community that the CYPHER stent has a "drug free topcoat" consisting of a polymer only.

(3) For purposes of this proceeding only (i.e., the court will revisit claim construction as the record develops), the court construes the disputed claim limitations consistent with BSC and finds, based on Cordis' promotional materials, that it is likely that BSC could prove infringement at trial. Nevertheless, the court also concludes that there is a substantial question as to the validity of the '536 patent, based

[4]According to Cordis, the CYPHER stent starts with a primer coat. A base coat consisting of two polymers, PBMA and PEVA, together with sirolimus, is then applied to the stent over the primer coat. These three ingredients are dissolved in a liquid solvent, THF, which is sprayed onto the stent. The solvent then evaporates and leaves behind a coating with the drug and two polymers mixed together. A top coat consisting of the polymer PBMA is dissoved in the same solvent, THF, which is then sprayed onto the base coat. When the application of the top coat begins, the solvent THF causes some of the base coat to dissolve and causes some sirolimus to move into the outer layer. The dissolution of the base coat and the movement of the sirolimus from the base coat to the top coat occurs before manufacture of the stent is completed. Although the amount of sirolimus in the top coat can be determined by laboratory testing of the top coat, there is no evidence to this effect in the record.

on the testimony of Dr. Hanson.[5] Therefore, as to the first prong of the analysis, the court concludes that BSC has not carried its burden of proof[6] and BSC's motion for injunctive relief is denied.

5. Therefore, IT IS ORDERED that:

a. The motion for a preliminary injunction filed by Cordis Corporation in C.A. No. 03-027-SLR (D.I. 8) is denied.

b. The motion for a preliminary injunction filed by Boston Scientific Scimed, Inc. and Boston Scientific Corporation in C.A. No. 03-283-SLR (D.I. 8) is denied.

Sue L. Robinson
United States District Judge

[5]See the July 23, 2003 hearing transcript at 728-759.

[6]Even if the court found that the first prong of the inquiry were satisfied, the court agrees with BSC that neither BSC nor Cordis should be granted a preliminary injunction on the current record, given the acknowledged public interest in a competitive medical device market and the absence of proof of irreparable harm to either company if their respective drug-eluting stents were introduced into a competitive market.